

Int'l. Appln. No.: PCT/EP00/09509
Docket No. B45201

- 31 30. A vaccine composition according to claim ³⁰~~29~~ wherein the amount of aluminium phosphate exceeds the amount of aluminium hydroxide.
- 32 31. A vaccine composition according to claim ²⁹~~28~~ wherein the aluminium salts are present in the range 0.4 to 1.0 µg per vaccine dose.
- 33 32. A vaccine composition according to claim ²⁷~~26~~ in which the low antigen dose is less than 10 µg of haemagglutinin per dose or per combined dose of vaccine.
- 34 33. A vaccine composition according to claim ³³~~32~~ in which the antigen dose is between 0.1 µg and 7.5 µg or between 1 and 5 µg of haemagglutinin per dose or per combined dose of vaccine.
- 35 34. A vaccine composition according to claim ²⁷~~26~~ wherein the influenza virus antigen is substantially free of host cell contamination.
- 36 35. A vaccine composition according to claim ²⁷~~26~~ wherein the influenza virus component is purified by a method which includes a protease incubation step to digest non-influenza virus proteins.
- 37 36. A kit comprising:
- (i) a low dose of influenza virus antigen formulated with an adjuvant suitable for parenteral administration; and
 - (ii) a low dose of influenza virus antigen for mucosal administration, in a mucosal delivery device such as an intranasal spray device.
- 38 37. The kit according to claim ³⁷~~36~~ wherein the combined antigen dose of the parenteral and mucosal formulations is no more than 15 µg haemagglutinin.
- 39 38. The kit according to claim ³⁸~~37~~ wherein the combined antigen dose is less than 10 µg haemagglutinin.
- 40 39. The kit according to claim ³⁸~~37~~ wherein the influenza antigen in (i) is inactivated whole virus and the influenza antigen in (ii) is split virus.

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41 40. The kit according to claim ~~37~~³⁸ wherein the parenteral adjuvant is an aluminium salt or salts.

~~42~~ 41. A method for the production of an influenza vaccine for a pandemic situation which method comprises admixing egg-derived influenza virus antigen from a single influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, with a suitable adjuvant and providing vaccines lots or vaccine kits which contain less than 10 µg influenza haemagglutinin antigen per dose or no more than 15 µg haemagglutinin per combined dose.

~~43~~ 42. A method according to claim ~~41~~⁴² wherein the antigen is highly purified.

~~44~~ 43. A method according to claim ~~41~~⁴² wherein the influenza virus antigen is in the form of whole influenza virus particles.

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~~45~~ 44. The vaccine composition of claim ~~26~~²⁷ wherein the antigen is selected from an H2 antigen such as H2N2 and an H5 antigen such as H5N1.

~~46~~ 45. The kit of claim ~~36~~³⁷ wherein the antigen is selected from an H2 antigen such as H2N2 and an H5 antigen such as H5N1.

~~47~~ 46. The method of claim ~~41~~⁴² wherein the antigen is selected from an H2 antigen such as H2N2 and an H5 antigen such as H5N1.

~~48~~ 47. A process for producing influenza virus antigen for use in a vaccine, which process comprises the step of incubating a mixture containing influenza virus particles with a protease to digest non-influenza virus proteins.

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~~49~~ 48. A method according to claim ~~47~~⁴⁸ wherein the protease digestion step is performed after the influenza virus antigen has been partially purified by one or more physical separation steps.

~~50~~ 49. A method according to claim ~~47~~⁴⁸ wherein the protease digestion step is performed prior to a virus inactivation step.

~~51~~ 50. A method according to claim ~~49~~⁵⁰ wherein the purification process comprises the steps of: